UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, Defendants.	No. 25-CV-00849-EP-JRA

DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A STAY OF INJUNCTION PENDING APPEAL

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Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and Novadoz Pharmaceuticals LLC (collectively, "MSN"), respectfully submit this reply memorandum of law in further support of its Motion to Stay the Court's Preliminary Injunction Order ("Order") pending appeal.

PRELIMINARY STATEMENT

MSN has demonstrated that this Court should grant a stay of its Order to preserve meaningful appellate review. MSN is likely to succeed in showing that the Court (i) erred in its consideration of the legal framework and evidence necessary to show irreparable harm, (ii) misapplied substantive trademark law on functionality and secondary meaning, and (iii) did not make a required determination that Novartis was likely to prevail on all four preliminary injunction factors.

Novartis's opposition asks the Court to ignore these errors and simply rubber stamp its prior decision. ECF 42 ("Stay Opp.") at 9–10. But Novartis's theory of "irreparable harm" lacked a proper evidentiary foundation and rested on mere generalities about its "good reputation" and non-specific observations that some generic drug manufacturers (not MSN) have experienced manufacturing defects. All of this is untethered to any cogent theory of real-world confusion among sophisticated prescribers, which is what trade dress law guards against.

The remaining stay factors favor MSN. Novartis has not controverted this Court's finding that the Order would irreparably harm MSN, including by causing

significant financial and developmental setbacks. Novartis's speculation that MSN's competitor Noratech is not poised to launch its drug is unsupported and contradicted by the record evidence. *See* Stay Opp. at 8–9. An injunction against MSN singles out MSN from all other generic competitors and threatens its first-mover advantage. And there is no reasonable dispute that the alleged harm to Novartis, should MSN launch its generic drug pending trial, would be compensable by monetary damages through a straightforward calculation of any lost profits. The balance of equities favors MSN because Novartis will incur minimal harm from a stay. Finally, the public interest favors a stay allowing MSN to market its affordable product.

Novartis's opposition portrays MSN's stay motion as seeking to alter to the status quo.[1] But the status quo is "the last uncontested status which preceded the pending controversy." *PTT, LLC v. Gimme Games*, 2014 WL 5343304, at *5 (D.N.J. Oct. 20, 2014). The status quo that existed before this action was filed was this: (i) MSN had received FDA approval to launch its generic ahead of other generics; and (ii) Novartis had never asserted its supposed "trade dress" rights in the three colors,

[1] Novartis also characterizes a stay as "extraordinary" and "disrupt[ive]" relief, Stay Opp. at 1, but district courts in multiple circuits have stayed preliminary injunctions where "equity tips in the defendants' favor." *Celgard, LLC v. LG Chem Am., Inc.*, 2014 WL 12479436, at *1 (W.D.N.C. July 22, 2014); *see also, e.g.*, *Illumina, Inc. v. BGI Genomics Co.*, 2020 WL 4601625, at *2–3 (N.D. Cal. Aug. 11, 2020); *Masters Software, Inc. v. Discovery Commc'ns, Inc.*, 2010 WL 11692803, at *4–5 (W.D. Wash. Aug. 13, 2010). This Court should do the same.

three sizes, and oval shape of its Entresto tablets and thus threatened to nullify MSN's years of investment and efforts to launch the first generic.[2]

ARGUMENT

I. MSN Is Likely to Succeed on the Merits of Its Appeal.

MSN is likely to succeed in showing that the Court erred both in its analysis of irreparable harm and in its analysis of Novartis's trade dress theory.

A. Novartis Failed to Demonstrate Irreparable Harm.

1. The Court Applied the Wrong Legal Framework to Assess Irreparable Harm.

Novartis does not dispute that the Court applied the wrong legal framework to assess irreparable harm. And contrary to Novartis's contention, application of this erroneous standard did not favor MSN but instead distorted the Court's analysis throughout. Because it sidestepped the statutory burden-shifting framework, the Court never evaluated the strength of Novartis's *evidence* of reputational harm and never made any finding that such evidence was sufficient to demonstrate irreparable harm. In effect, the Court credited a *theory* of reputational harm untethered to the evidence and applied an *irrebuttable* presumption of harm applicable in any trademark case. *See* ECF 37-1 ("Mot.") at 8–10. This contravenes Third Circuit law. *See Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 184–87 (3d Cir. 2022).

[2] MSN anticipates that the Delaware court will promptly lift its injunction, making a stay even more essential here so that MSN can seek meaningful appellate relief.

2. MSN Rebutted Any Presumption of Harm.

As MSN's moving papers explained, Third Circuit law instructs that the statutory presumption is rebutted upon a "*slight* evidentiary showing" that irreparable harm is unlikely. *Nichino*, 44 F.4th at 186. Even if Novartis were entitled to the presumption (and it was not, because it did not show a likelihood of success on the merits), MSN offered more than enough evidence to rebut the presumption. MSN demonstrated that Novartis's egregious delay of four years (or five months at minimum) rebutted the presumption of harm. *See* ECF 13 ("PI Opp.") at 33–35; Mot. at 8–9, 15–17. And MSN offered evidence that highly sophisticated healthcare professionals were unlikely to confuse the products. *See* PI Opp. at 24. This was sufficient to rebut the presumption.

Unable to address these arguments head on, Novartis urges the Court to ignore them because they are purportedly "new." Stay Opp. at 10, 19, 22–23.[3] But MSN is arguing nothing new. MSN has argued throughout this case that there is insufficient evidence of irreparable harm. In its motion for a stay, MSN contends that the Court's finding of irreparable harm cannot be reconciled with the Court's

[3] At the same time, Novartis seeks to have it both ways: Novartis repeatedly claims that the Court should disregard arguments MSN *did* previously raise because they are impermissible attempts to relitigate the preliminary injunction. *See* Stay Opp. at 1. This makes no sense. In its stay motion, MSN must demonstrate that it is likely to succeed on its appeal, and the arguments MSN will raise in its appeal are necessarily those that it raised and preserved in the initial preliminary injunction briefing.

finding that "the relevant market consists primarily of medical professionals, not consumers." Mot. at 9; *see also* ECF 32 ("Op.") at 14. MSN is entitled to point out on appeal that the Court's own findings establish that Novartis's theory is speculative and implausible.

Similarly, Novartis's contention that MSN raised "new" arguments regarding Novartis's delay is belied by the record. MSN raised the issue of Novartis's prior knowledge in its opposition to Novartis's motion. *See* PI Opp. at 34; ECF 13-9 ¶¶ 5–6, 9 & Exs. 3, 5. MSN did so because Novartis, in its initial submission, inaccurately claimed that it first obtained actual knowledge of the appearance of MSN's pills in August 2024. *See* ECF 4-1 ("PI Mot.") at 11 n.11; ECF 4-6 ¶ 10. When MSN called Novartis out, Novartis then changed course and argued *for the first time* in its reply that its hands were tied by the protective order. *See* ECF 17.

Nor were Novartis's hands actually tied. A protective order does not excuse complete inaction in response to facts purportedly giving rise to a claim. *See Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. Kg.*, 448 F. Supp. 2d 244, 264–65 (D. Mass. 2006), *aff'd*, 510 F.3d 77 (1st Cir. 2007). As in *Cambridge*, Novartis could have sought relief from the protective order.[4]

[4] Novartis's attempt to distinguish this case is highly unpersuasive. *See* Stay Opp. at 19–20. That Novartis is represented by different counsel of record in this case and in the patent litigation is irrelevant, because the protective order gave Novartis's *in-house counsel* access to the information at issue. And it is simply not true that, in

Even if Novartis's hands were tied by the protective order, it is undisputed that Novartis waited five months to sue *after* it was free from any constraint purportedly imposed by the protective order. That delay was inexcusable. Novartis cannot justify its five-month delay after reviewing public images of MSN's pills with no confidentiality restrictions by relying on inapposite cases involving a party's "good faith efforts to investigate" the claim. Stay Opp. at 21. In all of Novartis's cited cases, the plaintiff took *some steps* to identify or address the infringement. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 129 F. Supp. 2d 351, 368 (D.N.J. 2000) (plaintiff "promptly" challenged advertisements and commissioned survey); *Sunquest Info. Sys., Inc. v. Park City Sols., Inc.*, 130 F. Supp. 2d 680, 698 (W.D. Pa. 2000) (plaintiff "immediately" hired legal counsel to investigate extent of defendant's willful use); *Fisher-Price, Inc. v. Well-Made Toy Mfg. Corp.*, 25 F.3d 119, 125 (2d Cir. 1994) (plaintiff commenced months-long search for infringing product and sued "less than two weeks" after securing and obtaining infringing product). Here, Novartis did nothing for five months. That inexcusable delay rebuts any presumption of irreparable harm.

3. Novartis's Claimed Harm Is Speculative and Reparable.

Cambridge, the plaintiff had sufficient other facts in hand to assert its claim in a timely fashion. Rather, the court faulted the plaintiff for *failing* "to seek to obtain the same information . . . from other sources, such as depositions or letter rogatories." 448 F. Supp. 2d at 264. Novartis similarly failed to do so here.

Novartis needed to provide *evidence* demonstrating that irreparable harm was not merely possible but likely. *See* Mot. at 9–10. Considering itself bound by a "theory," the Court erred by failing to meaningfully review the evidence. *See id.*

Novartis's brief makes it abundantly clear that there is no non-speculative basis for finding irreparable harm here. Novartis's evidence consists entirely of general statements that (1) Novartis has a good reputation, (2) "medical professionals . . . *can* inadvertently confuse the MSN Drug and ENTRESTO," and (3) generic medicines "may not" always result in the same clinical outcomes as their branded counterparts and "can" have different negative side effects (even though upon approval, generic drugs are deemed bioequivalent to the brand drug product). Stay Opp. at 13–14 (emphasis added). This is a far cry from proving a risk of harm tied to *MSN's product specifically*, let alone one that is "more likely than not" to arise "while proceedings are pending."[5] *Delaware State Sportsmen's Ass'n, Inc. v. Delaware Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 204 (3d Cir. 2024).[6]

[5] MSN is not arguing for a standard that would require trademark owners to wait for irreparable harm to occur before seeking relief. *See* Stay Opp. at 13. Novartis failed to meet its burden because it presented no evidence of imminent harm on the facts of this case. This is unlike *AstraZeneca* where the defendant had launched a second wave generic with an aggressive advertising campaign intended to cause confusion with AstraZeneca's registrations for the color purple. *See Astrazeneca AB v. Camber Pharms., Inc.*, 2015 WL 7307101, at *5 (D. Del. Nov. 19, 2015).

[6] By contrast, each of Novartis's cited cases involved actual record evidence of harm. *OTR Wheel Eng'g, Inc. v. W. Worldwide Servs., Inc.*, 602 F. App'x 669, 672 (9th Cir. 2015) (acknowledging that "the court's finding of goodwill injury was

Indeed, Novartis fails to explain how any reputational harm could actually arise in real life. It does not explain why any doctor, knowing a patient had received MSN's generic drug, would irrationally blame *Entresto* for the patient's adverse health reaction simply because the doctor at some point saw images of MSN's pills on Drugs.com that look similar to Entresto. *See* Mot. at 13.

Finally, Novartis continues to miss the point about the import of *Becerra*. The factual theory of harm that *Becerra* rejected—that patients will be harmed by the dosing information on MSN's label—is exactly the same as the one Novartis advances here. The *Becerra* court endorsed FDA's rejection of that theory, "set forth in 10-pages of highly technical analysis," *Novartis Pharms. Corp. v. Becerra*, 2024 WL 3823270, at *6 (D.D.C. Aug. 13, 2024), and the Court here, in turn, endorsed *Becerra* as "well-reasoned," Op. at 17. Novartis provides no new evidence here that would warrant revisiting *Becerra*'s factual analysis and conclusions.

B. Novartis Failed to Demonstrate Likelihood of Success on its Trade Dress Claim.

1. The Court's Nonfunctionality Finding was Based on an Error of Law.

The Court's holding on functionality will likely be reversed on appeal because

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supported by some record evidence"); *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 205 (3d Cir. 2014) (characterizing "literally false, unsubstantiated comparative claims" as the "most important[]" record evidence supporting finding of likely irreparable harm); *MarbleLife, Inc. v. Stone Resources, Inc.*, 759 F. Supp. 2d 552, 562–63 (E.D. Pa. 2010) (relying on witness testimony).

it is directly contrary to the governing legal standard. The Court found that Entresto's appearance "has an element of functionality" because it "serve[s] as [a] useful visual cue[] for patients, particularly more vulnerable populations such as the elderly or others with comorbidities," and particularly because the drug is "to be taken in seeming perpetuity." Op. at 9. But the Court nevertheless held that the Entresto trade dress was likely nonfunctional because, "[s]imply put, MSN could have just picked different colors. Or different shapes. Or different sizes." *Id.* This directly contravened controlling Third Circuit precedent holding that, to be functional, a product feature "need only be useful, not essential," and that a useful product feature is functional "even when there are alternatives." *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, 986 F.3d 250, 258, 260 (3d Cir. 2021).

Unable to cure this straightforward error, Novartis ties itself into knots attempting to rewrite the Court's decision. Novartis claims, for example, that the Court's finding was not about Entresto but simply a "generalized statement about medications." *See* Stay Opp. at 26–27. But the Court's reference to a drug "to be taken in seeming perpetuity" by "the elderly or others with comorbidities" clearly describes Entresto. Op. at 9. Indeed, the Court's statement directly follows a lengthy description of the evidentiary record in *this case* about *Entresto*. *See* Op. at 7–9.[7]

[7] The Court did not credit the position that drug shape and color only help "identify the *brand* of a prescribed medication." Stay Opp. at 26 (citing Op. at 7–8).

Novartis also claims the purported availability of alternatives was somehow not the basis for the Court's ruling. *See* Stay Opp. at 24–25. But Novartis points to no other evidence that could have supported a finding of nonfunctionality. Novartis's *ipse dixit* that the Entresto trade dress "lack[s] functionality" and does "not confer an 'edge in usefulness,'" *id.* at 25, cannot justify the Court's holding.

Novartis's attempt to justify the Court's failure to apply *Shire US Inc. v. Barr Lab'ys, Inc.*, 329 F.3d 348 (3d Cir. 2003) also fails. The Court found that pill appearance "serve[s] as [a] useful visual cue[]" for the populations that take Entresto, Op. at 9, just as the Court in *Shire* did for populations that take Adderall. That Adderall patients and Entresto patients rely on visual cues for different reasons is irrelevant—in either case, the visual cues are "useful" to patients. And because Entresto patients are exposed to multiple dosages when they progress from a lower dose to a higher one (and sometimes back down to a lower dose), color-coding provides a functional benefit even if they are not taking different doses in one day.[8]

The Court also erred in failing to address the unrebutted evidence demonstrating the functionality of pill sizes and shapes. Novartis's response that

[8] Novartis's reliance on *Qualitex Co. v. Jacobson Products Co.*, 514 U.S. 159 (1995), is misplaced. In *Qualitex*, the functional benefit of avoiding noticeable stains could be achieved by using any color. Here, by contrast, as a generic provider, MSN could achieve the functional benefit of helping existing Entresto patients identify the correct drug only by using colors similar to those Entresto patients had become accustomed to.

this evidence was about *MSN's* pills rather than Entresto, *see* Stay Opp. at 28–29, ignores that the burden was on *Novartis* to provide evidence that Entresto pills' oval shape and dosage sizes were *nonfunctional*. The Court cited no such evidence, nor does Novartis in its filing. And in any event, evidence that MSN's pill shape and sizes are functional because they are easier to manufacture and swallow reasonably raises the inference that the same is true of Entresto's similar pill shape and sizes.[9]

Finally, Novartis's efforts to minimize the Court's error in ignoring key evidence are unavailing. The Court never addressed the Shimer declaration explaining FDA guidance that directs generic drugs to use similar sizes and shapes as their branded counterparts. *See* Op.; ECF 13-46. And the Court never confronted the anticompetitive consequences of its decision given evidence that *every other* potential entrant in the generic Entresto market for which this information is publicly available also modeled the appearance of its medication on that of Entresto.[10] Novartis's unsupported speculation that "it is possible" other manufacturers "opted

[9] It is thus irrelevant that "a combination of functional and non-functional features can be protected as trade dress." Stay Opp. at 29. Here, *every* feature of Novartis's claimed trade dress—color, shape, and size—is functional.

[10] In trying to circumvent this evidence, Novartis simply confirms that MSN is in the same position as those other generic manufacturers. For example, Novartis makes much of the fact that two other manufacturers used "off white" or "light pink" for the 24 mg/26 mg dose, instead of Entresto's "violet white." Stay Opp. at 31. But MSN does not use "violet white" either: MSN uses a darker purple color (and a pill size that is 25% smaller than Entresto's). *See* ECF 13-7 ("Nithiyanandam Decl.") & Ex. 1. Torrent uses an oval shape for two of its three pills. *See id.* And Alembic's capsules are also oval and thus infringing under Novartis's theory.

for different" pill configurations is wishful thinking. Stay Opp. at 32.

2. Novartis Failed to Meet Its Burden to Show Secondary Meaning.

Novartis did not show that each of the three common colors and non-distinctive ovaloid shape and sizes of Entresto tablets had come to be associated exclusively with Novartis *as a source identifier* among any substantial portion of the relevant consumer population. *See* Mot. at 22–24.

First, regarding exclusivity of use, Novartis's opposition distorts MSN's argument as claiming the Court should have evaluated "the entire pharmaceutical market." Stay Opp. at 33. This is a straw man. The Court erred by improperly defining the relevant market to include *only Entresto*, thereby conflating the exclusivity conferred by patent law with the exclusivity relevant for purposes of secondary meaning. Mot at 24. This error led the Court to disregard the significant, unrebutted evidence of widespread third-party use of the claimed trade dress features for the very kinds of medications that consumers of Entresto would likely be exposed to. *Id.* at 23. Novartis's opposition is silent on these points. *See* Stay Opp. at 33.

Second, Novartis fails to dispute that the Court committed clear error when it found as factual matter that Novartis's advertisements described the claimed trade dress in words, *i.e.*, directed the attention of the relevant consumers in text or spoken words to the colors, sizes and shapes of Entresto, alone or in combination. Mot. at 25. No such evidence was presented to the Court. To the contrary, the advertising

materials Novartis submitted showed the opposite. *See* ECF 4-44; ECF 4-58; ECF 4-59; ECF 4-78. The absence of relevant advertising favored MSN.

Third, Novartis fails to dispute that the Court erred in relying on the declaration of its paid expert, Dr. Nayeri, as support for a finding that the relevant consumers associated the claimed trade dress with a single source. Mot. at 27–28; Stay Opp. at 32–34. On this key factor—direct evidence of secondary meaning—not a single piece of probative evidence was presented to the Court. Where a party with ample financial resources like Novartis fails to present any consumer survey or other direct evidence of secondary meaning, this weighs strongly against a finding of secondary meaning. *See King of Prussia Dental Assocs., Ltd. v. King of Prussia Dental Care, LLC*, 2019 WL 2240492, at *12 (E.D. Pa. May 23, 2019).

Novartis fell far short of meeting its "formidable burden of proof" on this key issue. 1 McCarthy on Trademarks and Unfair Competition § 8:8.50 (5th ed.). Its pills are standard-issue oval tablets; the market is flooded with similar yellow, violet, and pink colored tablets; there was no evidence that Novartis had ever considered these colors to be proprietary (unlike AstraZeneca, which built an entire advertising campaign around the "Purple Pill" and secured federal trademark registrations for the color purple); the sizes of Entresto pills are utterly non-distinctive; and there was no direct evidence of secondary meaning. The Court thus erred in holding that Novartis demonstrated that it owned a valid and protectable trade dress.

C. The Court Erred in Considering the Balance of the Hardships and the Public Interest Factors.

A preliminary injunction requires *all four factors* to be satisfied. *See* Mot. at 30–31. The Court did not adequately analyze the balance of equities and public interest. The Court recognized that there is *actual evidence* of substantial hardship to MSN, including the loss of its first-mover advantage. Op. at 18. And it recognized that there are "societal benefits of affordable alternatives to brand-name drugs" and identified no public interest considerations favoring Novartis. Op. at 18.

Even if the Court's conclusion that MSN somehow brought the harm upon itself was correct (and it is not, *see* Mot. at 29–30), the only reasonable interpretation of the Court's Order is that the public interest prong weighed against a preliminary injunction. *See* Op. at 18. The Court never expressly found that Novartis wins on all four factors, as this Circuit requires. *See* Mot. at 7.

II. The Remaining Stay Factors are Satisfied.

The Court should grant a stay because MSN will be irreparably harmed by the Court's injunction. The Court recognized that MSN will suffer substantial hardship if enjoined. Op. at 18. Further, the record establishes that a preliminary injunction causing a delay in MSN's launch of its product will cause MSN to forfeit its first-mover advantage and lose the millions it has invested in research and development, as well as harm its reputation in the generic drug market. *See* Mot. at 32–33.

Novartis effectively concedes the substantial hardship to MSN, including the

loss of its first-mover advantage. *See* Stay Opp. at 35–36. Novartis's speculation that Noratech is not poised to launch its drug is without any support and contradicted by the record evidence before the Court. *See* Stay Opp. at 8–9. And to the extent that Novartis contends that Noratech would be similarly barred by the patent injunction, that is wholly inconsistent with Novartis's own position that the proceedings later this month could remove any patent-related obstacles to *any* generic's launch. *See* Stay Opp. at 5. A months- or years-long injunction against MSN pending final judgment in this case will thus have irreparable consequences, whereas any losses to Novartis are reparable as a matter of law.[11]

The balance of equities favors a stay: MSN will be gravely harmed by the injunction, whereas, as described above, Novartis's harm is minimal and speculative. Finally, the public interest favors a stay because it will allow MSN to market its affordable, safe, FDA-approved generic product to consumers.

CONCLUSION

For the foregoing reasons, the Court should grant MSN's motion.

[11] Novartis's argument that a one-week administrative stay of the preliminary injunction would be tantamount to total victory for MSN is nonsensical. *See* Stay Opp. at 38–39. If the Third Circuit declines to extend the stay, MSN will have to stop commercializing its product, and any lost sales suffered by Novartis in the one-week interim are fully compensable through money damages.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of March, 2025, I caused a copy of the foregoing to be served upon all counsel of record via ECF notification.

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